PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200201136 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00571	International filing date *(day/month/year)* 02.09.2003	Priority date *(day/month/year)* 02.09.2002

International Patent Classification (IPC) or both national classification and IPC
A61M39/08

Applicant
UNOMEDICAL A/S ET AL.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.04.2004	14.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Hedels, B Telephone No. +49 89 2399-2329

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00571

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-13 filed with telefax on 28.09.2004

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 13

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 13 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-12
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations

see separate sheet

Concerning item III.

The use claim 13 is superfluous since a device as defined in claim 1 is anyway used in the method of claim 9. Thus, claim 13 does not meet the requirement of conciseness (Art. 6 PCT).

Concerning item V.

1. Claim 1 has been delimited with respect to US-A-5 265822 (D1). Thus, the features specified in the preamble of claim 1 are disclosed in D1 (see Fig. 1).

The characterising features relating to the converging walls solve the objective problem of providing room for the wound-up tube for avoiding the risk of damage (see the description, page 7, lines 6-8).

The same problem is solved by converging walls in the device of US-A-4 802638 (D2) (see Fig. 8, the converging walls and reference numeral 170). The applicant's arguments that electrical cords disqualify as relevant prior art is not agreed, since electrical cords have to be protected against damage in the same manner as infusion tubes. The skilled person would therefore have considered the neighbouring field of cord stowing devices as disclosed in D2.

The skilled person would thus have provided the device of D1 with converging walls and he would thus have arrived at the subject-matter of claim 1 without the exercise of inventive skill. Hence, the subject-matter of claim 1 does not meet the requirement of inventive step (Art. 33(3) PCT).

2. The features of claims 2-5 are also disclosed in D1 and D2 (see the passages cited above and D2, column 2, line 9). Hence, these features are not inventive, too.

3. The arrangement of an attachment clip as defined in claims 6, 7 and 8 was general practice in this technical field (see US-A-5 984 224 (D3), the elements 36,38 or 40). The skilled person would have provided such a clip at the device of D1 without the exercise of an inventive step. Thus, these features are also not inventive.

4. The objection of lack of inventive step set out above with respect to claim 1 applies to the method claim 9 mutatis mutandis.

5. The features of the dependent claims 10-12 are also known from D1 and D2 (see the passages cited above) so that they are also not regarded as inventive.

6. The description should have been brought into line with the new claims (Rule 5.1 (a) (iii)).

7. D2 and D3 should in addition have been indicated in the description (Rule 5.1 (a) (ii)).

8. Figs. 6A-6C and Fig. 7 do not meet the requirement of Rule 11.13.

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Claims

1. An apparatus (1) for adjustment of the length of an infusion tube (2) comprising

- a first wall (3);
- a second wall (4);
- at least one slot (9) arranged in a wall (3, 4) such that an infusion tube (2) can pass through said wall (3, 4); and
- at least one connecting element (5) connecting said first wall (3) to said second wall (4),

said at least one slot (9) extending from the periphery (6) of said wall (3, 4) radially towards the internal area of the wall (3, 4); said connecting element (5) being secured at a distance to a peripheral circumference (6) of the walls; the apparatus further comprising an inlet opening (7) extending around the connecting element (5), said opening (7) being provided by a distance between said walls (3, 4) in a radial distance to said connecting element (5), **characterised in** that inner faces (10, 11) of the first and the second walls (3, 4) converge from the connecting element (5) out towards the inlet opening (7), said opening (7) having a with (M) measured between the walls (3, 4) adapted for allowing passage of a single infusion tube (2).

2. An apparatus according to claim 1, **characterised in** that the first and the second walls (3, 4) are identically configured bodies arranged in parallel and opposite to each other.

3. An apparatus according to claims 1 or 2, **characterised in** that the connecting element (5) comprises a cylindrical unit, the longitudinal axis of which is located perpendicular to the inner faces (10, 11) of the first and the second walls (3, 4).

4. An apparatus according to any one of claims 1-3, **characterised in** that the walls are, at least in the area delimiting the inlet opening (7), manufactured from an elastic material, e.g. a thermoplastic elastomer.

5. An apparatus according to any one of claims 1-4, **characterised in** that the entire apparatus is manufactured from an elastic material, e.g. a thermoplastic elastomer.

6. An apparatus according to any one of claims 1-5, **characterised in** that it further comprises an attachment device (21) integrated with the first (3) or second wall (4), for mounting the apparatus on a carrier face.

7. An apparatus according to claim 6, **characterised in** that the attachment device (21) is a clip device for mounting of the apparatus on a carrier face.

8. An apparatus according to claim 6 or 7, **characterised in** that the at least one slot (9) is formed in the wall (3, 4) in which the attachment device (21) for mounting the apparatus on a carrier face is arranged.

9. A method of adjusting the length of an infusion tube (2) using an apparatus (1) comprising

- a first wall (3);
- a second wall (4);
- at least one slot (9) arranged in a wall (3, 4) such that an infusion tube (2) can pass through said wall (3, 4); and
- at least one connecting element (5) connecting said first wall (3) to said second wall (4);

said at least one slot (9) extending from the periphery (6) of said wall (3, 4) radially towards the internal area of the wall (3, 4); said connecting element (5) being secured at a distance to a peripheral circumference (6) of the walls; said inlet opening (7) extending around the connecting element (5), said

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opening (7) being provided by a distance between said walls (3, 4) in a radial distance to said connecting element (5), said apparatus further comprising inner faces (10, 11) of the first and the second walls (3, 4) converging from the connecting element (5) out towards the inlet opening (7), said opening (7) having a with (M) measured between the walls (3, 4) adapted for allowing passage of a single infusion tube (2), wherein the tube (2) is pressed through the inlet opening (7) , such that a first portion (12) and a second portion (13) of the tube is caused to be situated outside the apparatus (1) and a third portion (14) is delimited by the walls (3, 4); wherein the entire or parts of the second portion (13) of the tube (2) is wound around the connecting element (5); and wherein the first and second end portions (12, 13) of the tube are secured in the slot (9) and/or the inlet opening (7).

10. A method according to claim 9, **characterised in** that the first portion (12) of the tube is secured in a slot (9) extending from the peripheral circumference (6) of the one wall and towards the internal area of the wall.

11. A method according to claim 9 or 10, **characterised in** that a free tube portion is secured at the delimitation of the inlet opening provided at the walls, said delimitation comprising a thermoplastic elastomer.

12. A method according to claims 9-11, **characterised in** that the second tube portion is secured in the slot (9) extending from the one peripheral circumference of the one wall and towards the internal area of the of the wall.

13. Use of apparatuses according to claims 1-8 for exercising the method according to claims 9-12.